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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,938	04/30/2001	Alexander V. Kabanov	3874-129 US	3307

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EXAMINER

LI, QIAN J

ART UNIT PAPER NUMBER

1632

DATE MAILED: 09/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,938

Applicant(s)

KABANOV ET AL.

Examiner

Q. Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 and 41-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-40 and 69-77 is/are rejected:
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election of Group III, drawn a method of administering a polynucleotide and a polyoxyethylene-polyoxypropylene block copolymer in a mammal, in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-28 and 41-68 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 14.

Claims 29-40 and 69-77 are under current examination.

Claim Objections

Claim 30 is objected to because of the following informalities: claim 30 depends from itself. Appropriate correction is required.

Claims 34-40 are objected to because they depend from a claim drawn to non-elected invention. Upon election of an invention for examination, said claim should be amended so that it only reads upon the elected invention. Appropriate correction is required.

Claims 70 and 72 are objected to because claim as written encompasses more than one invention, i.e. the composition used in the method encompassing the block

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copolymer alone or a combination of polyoxyethylene-polyoxypropylene block copolymer and other active components such as a polypeptide, which are drawn to an invention distinct from the elected invention. Upon election of an invention for examination, said claim should be amended so that it only reads upon the elected invention. Appropriate correction is required.

Claim 69 is objected to as substantially identical to claim 29. Applicant is advised that should claim 29 be found allowable, claim 69 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-40 and 69-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because the subject to which the composition is administered is missing, and thus the metes and bounds of the claims are unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29, 31, 32, 34, 36, 37, 39, 40, 69, 70, 72, 74-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Raz et al* (US 6,589,940), in view of *Kabanov et al* (5,656,611, IDS), and evidenced by *Jakob et al* (J Immunol 1998;161:3042-9).

Raz et al teach administering to a subject a polynucleotide (abstract), e.g. an immunostimulatory oligonucleotide (ISS-containing or CpG-containing oligodeoxynucleotides), preferably along with a block copolymer (column 17, line 27), and in the form of a colloidal dispersion (column 16, lines 55-59) for inducing immune response. They also teach that the preferred routes of administration are parenteral routes including intramuscular and intradermal injection (column 29, lines 3-11). Although not relied upon, *Jakob et al* teach that administering the CpG-containing polynucleotide would activate dendritic cells. *Raz et al* do not specifically teach the polyoxyethylene-polyoxypropylene block copolymer or the state of the block copolymer.

However, before the effective filing date of the instant invention, *Kabanov et al* teach using block copolymer in a polynucleotide composition for enhanced ability of nucleic acids crossing cell membranes and acting in the interior of a cell (abstract). *Kabanov et al* particularly teach the polyoxyethylene-polyoxypropylene block copolymer (e.g. columns 7 and 8), the state of the copolymer, and how to avoid gel formation of the composition (column 11).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Raz et al* by simply using the copolymer as taught by *Kabanov et al* in the method of *Raz et al* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because the copolymer could enhance the cell entry, thus, the efficacy of the polynucleotide. Thus, the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary.

Claims 29, 31, 32, 34, 36, 37, 39, 40, 69, 70, 72, 74-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Carson et al* (US 5,830,877), in view of *Kabanov et al* (5,656,611).

Carson et al teach a method for inducing immune response to an antigen comprising delivering a polynucleotide encoding the antigen to a host cell (column 7, lines 29-45) by intradermal or intramuscular injection of the polynucleotide. *Carson et al* also teach using cationic liposome to enhance gene delivery (column 3, lines 24-25). They go on to teach that the Th1 response induced by the polynucleotide is the result of

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antigen activation of antigen-presenting cells such as dendritic cells (column 7, § t.).

Carson et al do not specifically teach the polyoxyethylene-polyoxypropylene block copolymer or the state of the block copolymer.

However, before the effective filing date of the instant invention, *Kabanov et al* teach using block copolymer in a polynucleotide composition for enhanced ability of nucleic acids crossing cell membranes and acting in the interior of a cell (abstract). *Kabanov et al* particularly teach the polyoxyethylene-polyoxypropylene block copolymer (e.g. columns 7 and 8), the state of the copolymer, and how to avoid gel formation of the composition (column 11).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Carson et al* by simply using the copolymer as taught by *Kabanov et al* in the method of *Carson et al* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because the copolymer could enhance the cell entry, thus, the efficacy of the polynucleotide. Thus, the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary.

Claims 30, 33, 35, 38, 71, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Raz et al* (US 6,589,940) or *Carson et al* (US 5,830,877), and *Kabanov et al* (5,656,611) as applied to claims 29, 31, 32, 34, 36, 37, 39, 40, 69, 70, 72, and 74-77 above, further in view of *Kabanov et al* (6,218,438).

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The combined teachings of *Raz et al* or *Carson et al*, and *Kabanov et al* do not particularly teach a block copolymer comprising at least Pluronic F127 and L61. However, before the effective filing date of the instant invention, *Kabanov et al* teach that the block copolymers could be formulated with a biological agent comprising Pluronic F127 and L61 (Tabs 5 & 9).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Raz et al* or *Carson et al* and *Kabanov et al* ('611 patent) by simply using the specific Pluronic F127 and L61 copolymer as taught by *Kabanov et al* ('438 patent) in the method of *Raz et al* or *Carson et al* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because it is within the boundary of optimization of a copolymer formulation. Thus, the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29-40 and 69-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, 13, 18, 21, and 23 of U.S. Patent No. 6,359,054.

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims and claims of the cited patent are each drawn to a method comprising a polynucleotide or derivative thereof and at least one polyoxyethylene-polyoxypropylene block copolymer parenterally or intramuscularly in amounts insufficient for gel formation, wherein the composition comprising Pluronic L61 (claim 23) and F127 (Specification, 1st table in column 46), and forms aqueous dispersion.

Instant claims differ from claims of the cited patent in that the instant claims recite "inducing activation of dendritic cells" in the preamble, whereas claims of the cited patent recite "treating a patient". However, because the claimed method comprises the same method steps, administering substantially identical compositions, the method in the cited patent would perform the function of activating dendritic cells.

Accordingly, the claimed processes in the copending and the present application are obvious variants. Inventions as claimed are co-extensive.

Conclusion

No claim is allowed.

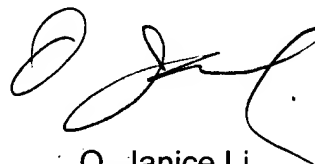
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

A handwritten signature in black ink, appearing to be 'Q. Janice Li', with a stylized, cursive script.

Q. Janice Li
Examiner
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QJL
September 8, 2003